

ATTORNEY'S DOCKET NO: 23800

U.S. DEPARTMENT OF COMMERCE, PATENT AND TRADEMARK OFFICE		DATE: <u>30</u> June 2000 ( <u>30</u> .06.2000)
TRANSMITTAL LETTER TO THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US) CONCERNING A FILING UNDER 35 U.S.C. 371		U.S. APPLN. NO. ( <u>Unknown</u> ) Not Yet Assigned <b>09/582700</b>
INTERNATIONAL APPLICATION NO.: PCT/US98/27380	INTERNATIONAL FILING DATE: 24 December 1998 (24.12.98)	PRIORITY DATE CLAIMED: 30 December 1997 (30.12.97)
TITLE OF INVENTION: <b>AN IRRIGATING MEDIUM FOR ROOT CANALS</b>		
APPLICANT(S) FOR DO/EO/US: MARAIS, Jacobus, Theodorus		
<p>Applicant hereby submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information:</p> <ol style="list-style-type: none"> <li><u>X</u> This is a <b>FIRST</b> submission of items concerning a filing under 35 U.S.C. 371.</li> <li><u>  </u> This is a <b>SECOND</b> or <b>SUBSEQUENT</b> submission of items concerning a filing under 35 U.S.C. 371.</li> <li><u>X</u> This express request to begin national examination procedures (35 USC 371(f)) at any time rather than delay examination until the expiration of the time limit set in 35 USC 371(b) and PCT Articles 22 and 39(1).</li> <li><u>X</u> A proper Demand for International Preliminary Examination was made by the 19th month from the earliest claimed priority date.</li> <li><u>X</u> A copy of the International Application as filed (35 U.S.C. 371(c)(2)):             <ol style="list-style-type: none"> <li><u>X</u> is transmitted herewith (required only if not transmitted by the International Bureau).</li> <li><u>  </u> has been transmitted by the International Bureau.</li> <li><u>  </u> is not required, as the application was filed in the United States Receiving Office (RO/US)</li> </ol> </li> <li><u>  </u> A translation of the International Application into English (35 U.S.C. 371(c)(2)).</li> <li><u>X</u> Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371(c)(3))             <ol style="list-style-type: none"> <li><u>  </u> are transmitted herewith (required only if not transmitted by the International Bureau).</li> <li><u>  </u> have been transmitted by the International Bureau.</li> <li><u>  </u> have not been made; however, the time limit for making such amendments has NOT expired.</li> <li><u>X</u> have not been made and will not be made.</li> </ol> </li> <li><u>  </u> A translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371(c)(3)).</li> <li><u>  </u> An oath or declaration of the inventor(s) (35 U.S.C. 371(c)(4)).</li> <li><u>  </u> A translation of the annexes to the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371(c)(5)).</li> </ol> <p><b>ITEMS 11. TO 16. BELOW CONCERN OTHER DOCUMENT(S) OR INFORMATION INCLUDED:</b></p> <ol style="list-style-type: none"> <li><u>  </u> An Information Disclosure Statement under 37 CFR 1.97 and 1.98.</li> <li><u>  </u> An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included.</li> <li><u>X</u> A <b>FIRST</b> preliminary amendment. <u>  </u> A <b>SECOND</b> or <b>SUBSEQUENT</b> preliminary amendment</li> <li><u>  </u> A substitute specification.</li> <li><u>  </u> A change of power of attorney and/or address letter.</li> <li><u>X</u> TRANSMITTAL FORM; FEE CALCULATION; INTERNATIONAL PUBLICATION WO99/34652; INTERNATIONAL PUBLICATION DATE 8 JULY 1999; PUBLISHED APPLICATION CONSISTING OF 19 PAGES INCLUDING 1 COVER PAGE CONTAINING THE ABSTRACT; 15 PAGES TEXTUAL SPECIFICATION; 3 PAGES OF 10 CLAIMS; 0 SHEETS DRAWINGS; PCT/ISA/210 INTERNATIONAL SEARCH REPORT; PRELIMINARY AMENDMENT; UNEXECUTED INVENTOR'S DECLARATION; PCT/IPEA/416 NOTIFICATION OF TRANSMITTAL OF INTERNATIONAL PRELIMINARY EXAMINATION REPORT; PCT/IPEA/409 INTERNATIONAL PRELIMINARY EXAMINATION REPORT; PCT/IB/308 NOTICE INFORMING THE APPLICANT OF THE COMMUNICATION OF THE INTERNATIONAL APPLICATION TO THE DESIGNATED OFFICES; COPY OF DEED OF ASSIGNMENT FILED WITH INTERNATIONAL BUREAU OF WIPO INDICATING TRANSFER OF RIGHTS; RESPONSE TO PCT WRITTEN OPINION FILED DEC. 13, 1999.</li> </ol>		

ATTORNEY'S DOCKET NO: 23800

U.S. APPLICATION NO. (if known) <b>09/582700</b>	INTERNATIONAL APPLICATION NO. PCT/US98/27380	DATE: <b>30</b> June 2000 ( <b>30</b> .06.2000)
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17. <u>x</u> The following fees are submitted:  <b>Basic National Fee (37 CFR 1.492(a)(1)-(5):</b> Search Report has been prepared by the EPO or JPO:.....\$840.00  <b>International preliminary examination fee paid</b> to USPTO (37 CFR 1.482).....\$670.00  <b>No international preliminary examination fee paid</b> to USPTO (37 CFR 1.482) but international search fee paid to USPTO (37 CFR 1.445(a)(2)).....\$760.00  <b>Neither international preliminary examination fee</b> (37 CFR 1.482) nor international search fee (37 CFR 1.445(a)(2)) paid to USPTO.....\$970.00  <b>International preliminary examination fee</b> (37 CFR 1.482) and all claims satisfied provisions of PCT Article 33(2)-(4).....\$ 96.00  <div style="text-align: right;"><b>ENTER APPROPRIATE BASIC FEE AMOUNT =</b></div>	<u>CALCULATIONS</u>	<u>PTO USE ONLY</u>
	\$ 96.00	
	\$ 96.00	

Surcharge of \$130.00 for furnishing the oath or declaration later than ____ 20 ____ 30 months from the earliest claimed priority date (37 CFR 1.492(e)).	\$	
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CLAIMS	NO. FILED	NO. EXTRA	RATE		
TOTAL	10 -20=	0	X \$ 18.00	\$	0.00
INDEPENDENT	32 - 3=	0	X \$ 78.00	\$	0.00
Multiple dependent claims(s) (if applicable)			+ \$260.00	\$	0.00
<b>TOTAL OF ABOVE CALCULATIONS =</b>				\$	96.00
Reduction by 1/2 for filing by small entity, if applicable. Verified Small Entity statement must also be filed. (Note 37 CFR 1.9, 1.27, 1.28).				\$	0.00
<b>SUBTOTAL =</b>				\$	96.00
Processing fee of \$130.00 for furnishing the English translation later than ____ 20 ____ 30 months from the earliest claimed priority date (37 CFR 1.492(f)).				\$	0.00
<b>TOTAL NATIONAL FEE =</b>				\$	96.00
Fee for recording the enclosed assignment (37 CFR 1.21(h)). The assignment must be accompanied by an appropriate cover sheet (37 CFR 3.28, 3.31). \$40.00 per property +				\$	0.00
<b>TOTAL FEES ENCLOSED =</b>				\$	96.00
				Amount to be:	
				refunded	\$
				charged	\$

ATTORNEY'S DOCKET NO:23800

U.S. APPLICATION NO. (if known) <b>09/582700</b>	INTERNATIONAL APPLICATION NO.  <b>PCT/US98/27380</b>	DATE: <b>30</b> June 2000 ( <b>30.06.2000</b> )
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a. ☒ One check in the amount of \$96.00 to cover the above fees is enclosed.

b. ☐ Please charge my Deposit Account No. 14-0112 in the amount of \$\_\_\_\_\_ to cover the above fees. (A duplicate copy of this sheet is enclosed.)

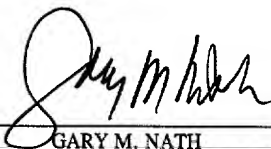
c. ☒ The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. 14-0112.

NOTE: Where an appropriate time limit under 37 CFR 1.494 or 1.495 has not been met, a petition to revive (37 CFR 1.137(a) or (b)) must be filed to request that the application be restored to pending status.

Send All Correspondence To:

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Rev. 02/98

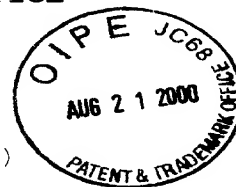
424 Recd PCT/US 2 AUG 2000

BOX PCT

Attorney Docket No. 23800

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:  
MARAIS, Jacobus Theodorus  
International Application No. PCT/US98/27380  
Serial No. 09/582700  
International Filing Date: 24 December 1998 (4.12.98)  
Filed: June 30, 2000  
For: **AN IRRIGATING MEDIUM FOR ROOT CANALS**



#3

TRANSMITTAL LETTER

Assistant Commissioner for Patents  
Washington, D.C. 20231

Sir:

Submitted herewith for filing in the U.S. Patent and Trademark Office is the following:

- (1) Transmittal Letter
- (2) Copy of Notification of Missing Requirements Under 35 U.S.C. 371
- (3) Response to Notification of Missing Requirements
- (4) Executed Declaration and Power of Attorney
- (5) Verified Statement Claiming Small Entity Status
- (6) Check No. 13279 \$ 65.00 surcharge for late filing of Declaration

The Commissioner is hereby authorized to charge any deficiency or credit any excess to Deposit Account No. 14-0112.

Respectfully submitted,

**NATH & ASSOCIATES PLLC**

By: 

Gary M. Nath  
Registration No. 26,965  
Jerard L. Meyer  
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Customer No. 20529

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Date: August 21, 2000  
**NATH & ASSOCIATES PLLC**  
1030 15<sup>th</sup> Street N.W., 6<sup>th</sup> Floor  
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GMN/JLM/dd:NEMP.TRANS

BOX PCT

Attorney Docket No. 23800

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re Application of:

Marais, Jacobus Theodorus

International Application No. PCT/US98/27380

Serial No. NOT YET ASSIGNED

International Filing Date: 24 December 1998 (24.12.98)

Filed: June 30, 2000

For: **AN IRRIGATING MEDIUM FOR ROOT CANALS**

**PRELIMINARY AMENDMENT**

The Assistant Commissioner for Patents  
Washington, D.C. 20231

Sir:

Before calculating the filing fee for the above identified application, please enter the following amendments:

**IN THE CLAIMS:**

Claim 4, line 1, delete "any one of the preceding claims"  
and insert in lieu thereof --claim 1--

Claim 5, line 1, delete "any one of the preceding claims"  
and insert in lieu thereof --claim 1--.

**REMARKS**

The above amendments have been made to remove multiple dependencies from the claims, and no new matter has been added.

Respectfully submitted,

**NATH & ASSOCIATES PLLC**

By: 

Gary M. Nath

Registration No. 26,965

Customer No. 20529

Date: June 30, 20000

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GMN/dd:AMENDpremPCT

Applicant: Jacobus Theodorus MARAIS

Atty Docket No. 23800

Serial No. 09/582,700

Filed: June 30, 2000

For: **AN IRRIGATING MEDIUM FOR ROOT CANALS**

VERIFIED STATEMENT (DECLARATION) CLAIMING SMALL ENTITY STATUS  
(37 CFR 1.9(F) AND 1.27(C) - SMALL BUSINESS CONCERN

I hereby declare that I am:

- ☐ the owner of the small business concern identified below  
☐ an official of the small business concern empowered to act on behalf of the concern identified below:

NAME OF CONCERN: **RADICAL WATERS IP (PTY) LTD**

ADDRESS OF CONCERN: Castleview South, 500 Tsitsa Street, Erasmuskloof, 0048, REPUBLIC OF SOUTH AFRICA

I hereby declare that the above-identified small business concern qualifies as a small business concern as defined in 13 CFR 121.3-18, and reproduced in 37 CFR 1.9(d) for purposes of paying reduced fees under Section 41(a) and (b) of Title 35, United States Code, in that the number of employees of the concern, including those of its affiliates, does not exceed 500 persons. For purposes of this statement (1) the number of employees of the business concern is the average over the previous fiscal year of the concern of the persons employed on a full-time, part-time, or temporary basis during each of the pay periods of the fiscal year, and (2) concerns are affiliates of each other when either, directly or indirectly, one concern controls or has the power to control the other, or a third party or parties controls or has the power to control both.

I hereby declare that rights under contract or law have been conveyed to and remain with the small business concern identified above with regard to the invention entitled **AN IRRIGATING MEDIUM FOR ROOT CANALS** by inventor(s) Jacobus Theodorus MARAIS described in

- ☐ the specification filed herewith  
☒ Application Serial No. 09/582,700 filed June 30, 2000  
☐ Patent No. issued

If the rights held by the above-identified small business concern are not exclusive, each individual, concern or organization having rights to the invention is listed below\* and no rights to the invention are held by any person, other than the inventor, who could not qualify as a small business concern under 37 CFR 1.9(d) or by any concern which would not qualify as a small business concern under 37 CFR 1.9(d) or a nonprofit organization under

37 CFR 1.9(e). \*NOTE: Separate verified statements are required from each named person, concern or organization having rights to the invention averring to their status as small entities. (37 CFR 1.278)

Full Name \_\_\_\_\_

Address \_\_\_\_\_

☐ Individual                      ☐ Small Business                      ☐ Nonprofit Organization

VERIFIED STATEMENT (DECLARATION) CLAIMING SMALL ENTITY STATUS  
(37 CFR 1.9(F) AND 1.27(C) - SMALL BUSINESS CONCERN

Page Two

Docket No. 23800

I acknowledge the duty to file, in this application or patent, notification of any change in status resulting in loss of entitlement to small entity status prior to paying, or at the time of paying, the earliest of the issue fee or any maintenance fee due after the date on which status as a small entity is no longer appropriate. (37 CFR 1.28(b))

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application, any patent issuing thereon, or any patent to which this verified statement is directed.

Name of Person Signing: J J Viljoen

Title of Person Signing DIRECTOR

Address of Person Signing: P O Box 6482, Halfway Hse, 1685, RSA.  
3/458 West St, Glen Austin, Ext 3, Mid Rand, RSA

Signature \_\_\_\_\_ Date 15-08-2000

TITLE:

AN IRRIGATING MEDIUM FOR ROOT CANALS**INTRODUCTION AND BACKGROUND TO THE INVENTION**

This invention relates to the use of antiseptics in root canal treatment so as to reduce the proliferation of bacteria and other micro-organisms remaining in the root canal after obturation.

5

Sodium hypochlorite is universally used as an antiseptic for root canal irrigation, its principal functions in root canal treatment being microbicidal, dissolving organic material and lubrication. However, a disadvantage of sodium hypochlorite is that it is highly toxic to human tissues and cells in concentrated form and potentially even fatal at the concentrations at which it is at its most effective as an irrigating medium.

10

**OBJECT OF THE INVENTION**

It is accordingly an object of this invention to provide a novel, relatively inexpensive and safe irrigating medium for root canals.

15

**SUMMARY OF THE INVENTION**

According to a first aspect of the invention there is provided the use of an aqueous solution in the preparation of an irrigating medium for use in the treatment of root canals, the aqueous solution being characterised in that it is electro-chemically activated. The electro-chemically activated aqueous solution may consist of an aqueous anion-containing and/or an aqueous

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cation-containing solution. The aqueous anion-containing solution and/or aqueous cation-containing solution may be prepared by means of electrolysis of an aqueous solution of a salt. The salt may be sodium chloride. In particular, it may be non-iodated sodium chloride or potassium chloride.

The anion-containing and the associated cation-containing solution may be produced by an electro-chemical reactor or so-called electrolysis machine. The anion-containing solution is referred to hereinafter for brevity as the "anolyte solution" and the cation-containing solution is referred to hereinafter for brevity as the "catholyte solution". The anolyte solution and the catholyte solution are preferably provided from an electro-chemical reactor comprising a through-flow, electro-chemical cell having two co-axial electrodes with a co-axial diaphragm between them so as to separate an annular inter-electrode space into cathodic and anodic chambers.

The anolyte solution may be produced from a 10% aqueous NaCl solution, electrolysed in the anodic chamber to produce activated or excited aqueous solutions containing numerous free radicals, the anolyte solution having an extremely high redox potential of up to about +1170 mV and a pH value of about 2-7. These activated radical species may be labile and after about 96 hours the various radical species may disappear with no residues being

produced.

The anolyte solution may include activated radical species such as  $\text{ClO}\cdot$ ;  $\text{ClO}^-$ ;  $\text{HClO}$ ;  $\text{OH}\cdot$ ;  $\text{HO}_2^-$ ;  $\text{H}_2\text{O}_2$ ;  $\text{O}_3$ ;  $\text{HO}\cdot$ ;  $\text{S}_2\text{O}_8^{2-}$  and  $\text{Cl}_2\text{O}_6^{2-}$ .

5

The activated radical species have been found to have a synergistic anti-bacterial and/or anti-viral effect which is generally stronger than that of chemical bactericides and has been found to be particularly effective against viral organisms, spore and cyst forming bacteria including Gram positive and Gram negative bacteria such as *Enterococcus faecalis* and *Pseudomonas aeruginosa*.

10

The catholyte solution generally may have a pH of up to about 7-13 and a redox potential of about -980 mV. The catholyte solution may include activated radical species such as  $\text{NaOH}$ ;  $\text{KOH}$ ;  $\text{Ca}(\text{OH})_2$ ;  $\text{Mg}(\text{OH})_2$ ;  $\text{HO}\cdot$ ;  $\text{H}_3\text{O}_2^-$ ;  $\text{HO}_2^-$ ;  $\text{H}_2\text{O}_2$ ;  $\text{O}_2^-$ ;  $\text{OH}\cdot$ ;  $\text{O}_2^{2-}$ .

15

It is believed that the activated oxidising radical species or free radicals present in the anolyte solution act synergistically as a biocidal and virucidal agent at a bacterial cellular level, while the activated reducing radical species or free radicals present in the catholyte solution act synergistically as a cleaning agent to dissolve organic material or biofilm protecting or

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covering micro-organisms and with the micro-organisms themselves.

It has been found that the efficacy of the use of the anolyte and/or catholyte solution in the preparation of an irrigating medium for use in the treatment of root canals depends upon the concentration of the anolyte and/or the catholyte solutions, as measured by the oxidation-reduction potential (ORP) or redox potential of the anolyte and/or the catholyte solution, the exposure time, i.e. the contact time between the root canal and the anolyte and/or the catholyte solutions and the temperature during application. Anolyte has been found to be more effective at lower than at higher temperatures.

According to a second aspect of the invention there is provided an irrigating medium for irrigating root canals, the irrigating medium comprising an aqueous solution being substantially as hereinbefore defined.

According to a third aspect of the invention there is provided a method for irrigating root canals including the step of applying an electro-chemically activated aqueous solution to a root canal, substantially as hereinbefore defined.

## DETAILED DESCRIPTION OF THE INVENTION

The method of irrigating root canals may include the steps of first applying catholyte solution to the root canal, aimed at removing organic biofilm and debris covering the inner walls of the root canal, and thereafter applying  
5 anolyte solution to the root canal, aimed at disinfecting the inner walls of the root canal and inner tubes in a tooth.

A preferred embodiment of the invention will now be described by means of two non-limiting examples.

### 1. Example No. 1

20 single rooted teeth were collected from the Department of Oral and Maxillofacial Surgery of the Faculty of Dentistry of the University of Pretoria, South Africa, immediately after extraction from patients' mouths.

#### 1.1 Testwork

The extracted teeth were rinsed under running potable water and stored in specimen bottles filled with distilled water for 24  
20 hours. The pulp chambers of the teeth were then accessed by the use of fissure burs in turbine handpieces and round burs in contra-angle handpieces.

5 A number 15 K-type root canal file was then introduced into each root canal to establish the patency of the canal. The exact length of each canal was determined by inserting a file into the root canal until its tip just appeared through the apical foramen. A silicone rubber stop pre-fitted to the shaft of the file was then adjusted to a coronal reference point, an intact part of the tooth.

10 The file was then withdrawn and the length from file tip to silicone stop was noted. An individual working length for each tooth was calculated by subtracting 1 mm from the measured length. The coronal thirds of all canals were pre-flared using Gates Glidden burs in a contra-angle handpiece. At this stage, 15 the 20 teeth were randomly divided into two groups, namely Group A and Group B, for irrigation with the conventional sodium hypochlorite and the electro-chemically activated solution (STEDS) in accordance with the present invention respectively, each group consisting of 10 teeth.

20

**Group A (sodium hypochlorite) :**

5 The root canals of Group A were prepared, using a series of K-type files (size 15-60) manually and by irrigating with a 2,5% solution of sodium hypochlorite, with an ultrasonic unit such as a so-called Cavi-Endo (Dentsply) unit. Irrigation was performed after the use of every size file for at least 10 seconds, using the same ultrasonic unit.

10 After the canal was prepared to a size 60, a final flush of irrigation was carried out for a minimum of 30 seconds. A minimum of 150 ml of 2,5% sodium hypochlorite was used in the irrigating process of each tooth.

**Group B (Electro-chemically Activated Solution "STEDS")**

15 STEDS was produced from a specially manufactured electro-chemical reactor, comprising a through flow, electro-chemical cell having two co-axial cylindrical electrodes with a co-axial diaphragm between them so as to separate an annular inter-electrode space into cathodic and anodic chambers. The  
20 STEDS produced included two separate solutions, namely catholyte and anolyte solutions. The anolyte solution had a pH of about 7.4 and a redox potential of about +1170 mV. The

catholyte solution had a pH of about 9,5 and a redox potential of about -980mV. These solutions were used to irrigate the canals in Group B. Root canals were prepared using the same size and types of files and the same manual techniques as in Group A. Initially the catholyte solution was used to irrigate the canals using the same ultrasonic unit as group B. After the use of each size file, the canal was irrigated with anolyte solution for at least 10 seconds.

After preparation to a size 60, a final flush of irrigation was carried out for a maximum of 30 seconds using catholyte solution. A minimum of 100 ml anolyte and 50 ml catholyte solutions were used for each tooth.

Immediately after the above preparation and irrigation procedures had been carried out, the teeth were again stored in distilled water for 24 hours. Each tooth was then dissected with the aid of a microtome. Specimens of the root canal walls of the middle third of the roots, measuring roughly 2 mm by 2 mm, were prepared. The specimens were handled with locking forceps throughout, eliminating contamination by human hand. The specimens were placed into a dust-free

incubator and allowed to air-dry for 10 days.

5 The air-dried specimens were mounted with conductive adhesive onto metal bases and coated with gold and viewed in a scanning electron microscope at various magnifications. The amount of remaining debris on the root canal walls were compared by noting the debris on the surfaces of twenty representative samples of each group.

10 1.2 Results

The remaining debris in Group B was negligible. Group A exhibited small but noticeable amounts of debris on the surface of a number of specimens. In group B, it was noticed that the so-called smear layer, clearly present in all samples of Group A, had been removed in large areas.

Under the conditions of this study, STEDS compared favourably as an irrigating material with sodium hypochlorite.

It removed a large degree of debris from the surfaces of the prepared root canal walls.



## 2. Example 2

### 2.1 Testwork

69 extracted teeth, had their root canals prepared in the same manner as in Example 1. The teeth were then sterilised by means of an autoclave and were placed under aseptic conditions in 200 ml of BHI (brain-heart infusion) liquid culture medium together with 1.0 ml of an overnight broth culture of each of the following organisms: *E.faecalis*, *P.aeruginosa* and *S.mutans*. The teeth were kept in this broth for 7 days in an incubator at 37° C.

At the end of the 7 day period, the teeth were removed with a pair of sterile forceps from the broth. The bioload was expected to be extremely high by this time and colony counts were performed on the broth by doing a series of 10-fold dilutions in triplicate. Aliquots of these dilutions (100 µl) were spotted on 10% blood agar plates and spread with a sterile metal spreader over the surface of the plates. After overnight incubation at 37°C, these plates were counted and the number of colony-forming units (cfus) estimated.

The teeth were washed together in a sterile bottle with 100 ml

of normal saline, repeated 4 times, with fresh saline being added after the contaminated saline was discarded. This reduced the bioburden to a level where the technologist carrying out the procedure was unlikely to develop an infection from spray aerosols.

5

The teeth were placed with the access cavity side facing upwards in sterile micro titre trays. Prior to treatment, all the teeth were "irrigated" down the access cavity with 50 ml sterile water using a syringe, for 5 minutes, this being similar to a manual irrigation procedure in the dental surgery. The teeth were then held upside-down for a few seconds to allow most of the water to drain off. The teeth were then divided into different groups for the various treatments.

10

15

Three groups of 20 teeth each were created, with three individual teeth serving as the catholyte control group and the six other teeth for whole tooth studies.

20

In Group A (negative control) all the teeth's root canals were irrigated with saline for 5 minutes, using a fine-needle tuberculin syringe. 30 µl saline was then aspirated from the

root canals, serially diluted and spread plated onto 10% blood agar plates and incubated at 37°C for 24 hours.

5 In Group B, 20 teeth were similarly treated with sodium hypochlorite for 5 and 10 minutes respectively. After 5 minutes and again after 10 minutes, the canals were filled with saline, and 30µl saline were then aspirated, diluted, plated, and incubated.

10 In Group C all teeth were first treated with catholyte for 5 minutes. After this time, the catholyte was rinsed off with anolyte solution. The teeth were then treated with anolyte for 5 and 10 minutes respectively. At the end of these periods, the same culturing procedure, using saline, was used to take  
15 samples from the root canals.

20 Whole tooth studies were conducted on six of the teeth, as mentioned above. Two of the teeth were stored in sodium hypochlorite and cultures taken after 5 and 10 minutes. The two remaining teeth were stored in the catholyte, rinsed with – and stored in the anolyte. Cultures were taken after 5 and 10 minutes storage time.

## 2.2 Results

### 2.2.1 Baseline counts

The broth was shown to contain  $4.4 \times 10^{10}$  cfus after 7 days' incubation with frequent additions of fresh culture medium.

The average numbers of organisms present in the root canals after treatment with saline only was  $1.4 \times 10^6$  cfus. The reason for this high count was that most of the organisms remained behind as a biofilm. An unexpected finding was that following catholyte treatment (with no anolyte), the count went up to  $2 \times 10^7$  cfus. This is presumably because catholyte is known to act in a similar way to a detergent, lifting the biofilm from the surface.

### 2.2.2 Test Products

#### AVERAGE NUMBER OF COLONY-FORMING UNITS IN ROOT CANALS OBTAINED AFTER EXPOSURE

	SODIUM HYPOCHLORITE	ANOLYTE
5 minutes exposure	0	400
10 minutes exposure	0	0

### 2.2.3 Whole Tooth Counts

When the teeth were treated with sodium hypochlorite only for 5 minutes, the average count was  $4 \times 10^2$  cfus. The counts dropped to zero when left for 10 minutes.

Using anolyte only (no catholyte pre-treatment) the average count was  $1.2 \times 10^5$ . However, when the teeth were exposed to catholyte, irrigated and then treated with anolyte for 10 minutes, the count dropped to zero.

This in vitro study shows that anolyte is highly effective in

eradicating both planktonic and sessile organisms adherent to the tooth surface.

It is important that catholyte be applied first and then the catholyte  
5 and the loosened biofilm **MUST** be rinsed off for really effective results with the anolyte treatment.

It will be appreciated that many variations in detail are possible without departing from the scope and/or spirit of the invention as defined in the  
10 claims hereinafter.

001280:00223960

## CLAIMS

1. Use of an aqueous solution in the preparation of an irrigating medium for use in the treatment of root canals, the aqueous solution being characterised in that it is electro-chemically activated.
2. The use as claimed in claim 1, wherein the electro-chemically activated aqueous solution includes an aqueous anion-containing and an aqueous cation-containing solution.
3. The use as claimed in claim 2, wherein the aqueous anion-containing solution and the aqueous cation-containing solution are prepared by means of electrolysis of an aqueous solution of a salt.
4. The use as claimed in any one of the preceding claims wherein the anion-containing and the cation-containing solution are produced by an electro-chemical reactor comprising a through-flow, electro-chemical cell having two co-axial electrodes with a co-axial diaphragm between them so as to separate an annular inter-electrode space into cathodic and anodic chambers.
5. The use as claimed in any one of the preceding claims wherein the

anion-containing solution is produced from a 10% aqueous NaCl solution, electrolysed to produce activated or excited radical cation and radical anion species, the anion-containing solution having an extremely high redox potential of up to about +1170 mV.

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6. The use as claimed in claim 5 wherein the anion-containing solution has a pH of about 2-7 and a redox potential of about +1170 mV.

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7. The use as claimed in claim 5 wherein the cation-containing solution has a pH of up to about 7-13 and a redox potential of about -980 mV.

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8. An irrigating medium for irrigating root canals, the irrigating medium comprising an electro-chemically activated, aqueous saline solution.

9. A method for irrigating root canals including the step of applying an electro-chemically activated, aqueous saline solution to a root canal for irrigation purposes.



10. The method as claimed in claim 9 including the steps of first applying cation-containing solution to the root canal, aimed at removing organic film and debris covering the inner walls of the root canal, and thereafter applying an anion-containing solution to the root canal, aimed at disinfecting the inner walls of the root canal and dentinal tubules.

## DECLARATION FOR PATENT APPLICATION

Attorney Docket: 23000  
Page 1 of 2

As a below named inventor(s), I/we hereby declare that:

My/Our residence(s), post office address(es) and citizenship(s) is/are as stated below next to my/our name(s).

I/We believe I/we am/are the original inventor, first and sole (if only one name is listed below) or the original, first and joint inventors (if plural names are listed below) of the subject matter which is claimed, and for which a patent is sought on the invention entitled:

**AN IRRIGATING MEDIUM FOR ROOT CANALS**

the specification of which: (check one)

☐ is attached hereto.☒ was filed on 24 Dec. 1998, as Serial No. PCT/US98/27380,  
30 June 2000 09/582,700  
and was amended on \_\_\_\_\_ (if applicable).

We hereby state that we have reviewed and understand the contents of the above identified specification, including the claims, as amended by any amendment referred to above.

We acknowledge the duty to disclose information which is material to the patentability of this application as defined by 37 CFR § 1.56.

We hereby claim foreign priority benefits under 35 U.S.C. § 119 of any foreign application(s) for patent or inventor's certificate listed below, and have also identified below any foreign application for patent or inventor's certificate having a filing date before that of the application on which priority is claimed:

## Prior Foreign Applications:

Application No.	Country	Day/Month/Year Filed	Priority Claimed
<u>97/11702</u>	<u>ZA</u>	<u>30 / Dec. / 1997</u>	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
_____ (Application No.)	_____ (Country)	_____ (Day/Month/Year Filed)	<input type="checkbox"/> Yes <input type="checkbox"/> No
_____ (Application No.)	_____ (Country)	_____ (Day/Month/Year Filed)	<input type="checkbox"/> Yes <input type="checkbox"/> No
_____ (Application No.)	_____ (Country)	_____ (Day/Month/Year Filed)	<input type="checkbox"/> Yes <input type="checkbox"/> No

We hereby appoint Gary M. Nath, Reg. No. 26,965; Harold L. Novick, Reg. No. 26,011; Todd L. Juneau, Reg. No. 40,669; Lee C. Heiman, Reg. No. 41,827; Jerald L. Meyer, Reg. No. 41,194; Joanna B. Goldberg, Reg. No. 44,126; David R. Murphy, Reg. No. 22,751; Paul A. Sacher, Reg. No. 43,418; Charles D. Niebyski, Reg. No. 46,116; Deborah H. Yelton, 45,904; Nahid K. Osman, Reg. No. 7-47,148; and Roger Hahn, Reg. No. 46,376; as my attorneys to prosecute this application and transact all business in the U.S. Patent and Trademark Office connected therewith.

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We hereby claim the benefit under 35 U.S.C. § 120 of any United States application(s) listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States application in the manner provided by 35 U.S.C. § 112, first paragraph, I/we acknowledge the duty to disclose material information as defined in 37 CFR § 1.56 which occurred between the filing date of the prior application and the national or PCT international filing date of this application:

(U.S. Application Serial No.)	(U.S. Filing Date)	(Status--patented, pending, abandoned)
_____ (U.S. Application Serial No.)	_____ (U.S. Filing Date)	_____ (Status--patented, pending, abandoned)

DECLARATION FOR PATENT APPLICATION	Attorney Docket: 23800 Page 2 of 2
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DECLARATION FOR PATENT APPLICATION	Attorney Docket: 23800 Page 2 of 2
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We hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements are made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under 18 U.S.C. § 1001 and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

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Inventor's Signature [Signature] Date 15/8/2000

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	1970-71	1971-72	1972-73	1973-74	1974-75	1975-76	1976-77	1977-78	1978-79	1979-80	1980-81	1981-82	1982-83	1983-84	1984-85	1985-86	1986-87	1987-88	1988-89	1989-90	1990-91	1991-92	1992-93	1993-94	1994-95	1995-96	1996-97	1997-98	1998-99	1999-00	2000-01	2001-02	2002-03	2003-04	2004-05	2005-06	2006-07	2007-08	2008-09	2009-10	2010-11	2011-12	2012-13	2013-14	2014-15	2015-16	2016-17	2017-18	2018-19	2019-20	2020-21	2021-22	2022-23	2023-24	2024-25	2025-26	2026-27	2027-28	2028-29	2029-30	2030-31	2031-32	2032-33	2033-34	2034-35	2035-36	2036-37	2037-38	2038-39	2039-40	2040-41	2041-42	2042-43	2043-44	2044-45	2045-46	2046-47	2047-48	2048-49	2049-50	2050-51	2051-52	2052-53	2053-54	2054-55	2055-56	2056-57	2057-58	2058-59	2059-60	2060-61	2061-62	2062-63	2063-64	2064-65	2065-66	2066-67	2067-68	2068-69	2069-70	2070-71	2071-72	2072-73	2073-74	2074-75	2075-76	2076-77	2077-78	2078-79	2079-80	2080-81	2081-82	2082-83	2083-84	2084-85	2085-86	2086-87	2087-88	2088-89	2089-90	2090-91	2091-92	2092-93	2093-94	2094-95	2095-96	2096-97	2097-98	2098-99	2099-00	2100-01	2101-02	2102-03	2103-04	2104-05	2105-06	2106-07	2107-08	2108-09	2109-10	2110-11	2111-12	2112-13	2113-14	2114-15	2115-16	2116-17	2117-18	2118-19	2119-20	2120-21	2121-22	2122-23	2123-24	2124-25	2125-26	2126-27	2127-28	2128-29	2129-30	2130-31	2131-32	2132-33	2133-34	2134-35	2135-36	2136-37	2137-38	2138-39	2139-40	2140-41	2141-42	2142-43	2143-44	2144-45	2145-46	2146-47	2147-48	2148-49	2149-50	2150-51	2151-52	2152-53	2153-54	2154-55	2155-56	2156-57	2157-58	2158-59	2159-60	2160-61	2161-62	2162-63	2163-64	2164-65	2165-66	2166-67	2167-68	2168-69	2169-70	2170-71	2171-72	2172-73	2173-74	2174-75	2175-76	2176-77	2177-78	2178-79	2179-80	2180-81	2181-82	2182-83	2183-84	2184-85	2185-86	2186-87	2187-88	2188-89	2189-90	2190-91	2191-92	2192-93	2193-94	2194-95	2195-96	2196-97	2197-98	2198-99	2199-00	2200-01	2201-02	2202-03	2203-04	2204-05	2205-06	2206-07	2207-08	2208-09	2209-10	2210-11	2211-12	2212-13	2213-14	2214-15	2215-16	2216-17	2217-18	2218-19	2219-20	2220-21	2221-22	2222-23	2223-24	2224-25	2225-26	2226-27	2227-28	2228-29	2229-30	2230-31	2231-32	2232-33	2233-34	2234-35	2235-36	2236-37	2237-38	2238-39	2239-40	2240-41	2241-42	2242-43	2243-44	2244-45	2245-46	2246-47	2247-48	2248-49	2249-50	2250-51	2251-52	2252-53	2253-54	2254-55	2255-56	2256-57	2257-58	2258-59	2259-60	2260-61	2261-62	2262-63	2263-64	2264-65	2265-66	2266-67	2267-68	2268-69	2269-70	2270-71	2271-72	2272-73	2273-74	2274-75	2275-76	2276-77	2277-78	2278-79	2279-80	2280-81	2281-82	2282-83	2283-84	2284-85	2285-86	2286-87	2287-88	2288-89	2289-90	2290-91	2291-92	2292-93	2293-94	2294-95	2295-96	2296-97	2297-98	2298-99	2299-00	2300-01	2301-02	2302-03	2303-04	2304-05	2305-06	2306-07	2307-08	2308-09	2309-10
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